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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,601	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3012/JEK/JJC	4601

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EXAMINER
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WIEKER, AMANDA FLYNN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/725,601

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Amanda F. Wieker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/3, 7/29, 8/13, 2/2.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: IDS 5/11.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the subject matter of claim 24 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable one skilled in the art to make and/or use the invention, comprising a pressure sensitive adhesive layer applied to a portion of the absorbent core. The specification fully enables the placement of a pressure sensitive adhesive on a portion of the facing layer, but does not disclose or enable placement of pressure sensitive adhesive at the location claimed in claim 24.

Claim 24 is also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above, the specification does not support the claimed pressure sensitive adhesive layer applied to a portion of the absorbent core. This claim was added in a preliminary amendment filed on 27 July 2004, and constitutes new matter that is not supported by the originally filed specification.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Number 2003/0199800 to Levin in view of U.S. Patent Number 6,566,575 to Stickels et al.

Levin discloses a wound dressing comprising:

an absorbent core (26) having opposed proximal and distal surfaces including central and border (edges) portions;

a discrete skin adherent, elastomeric gel facing layer (22) having a distal surface secured to the proximal surface of the absorbent core, said facing layer having a plurality of through extending apertures (24) arranged in a pattern; and

a discrete adhesive layer (40) applied adjacent the facing layer to secure the dressing to the wound.

Regarding claim 2, the plurality of apertures of the facing layer are generally located along a central portion thereof corresponding to the central portion of the absorbent core (see Figure 2).

Regarding claim 3, a border portion of the facing layer generally corresponding to the border portion of the absorbent core is substantially free of said apertures (see Figure 2).

Regarding claim 6, the adhesive had greater skin adherence than the elastomeric gel.

Regarding claims 19 and 20, the proximal and distal surfaces of the facing layer are generally planar.

Levin does not specify that the adhesive that secures the dressing to the wound be a pressure sensitive adhesive layer applied to the proximal surface of the facing layer.

Stickels et al. disclose a wound dressing comprising an absorbent core (12); a discrete facing layer (20) having a distal surface secured to the proximal surface of the absorbent core, said facing layer having a plurality of through extending apertures (24) arranged in a pattern; and a discrete pressure sensitive adhesive layer applied to the facing layer on at least a segment of a proximal surface thereof, to provide a secure adhesion of the dressing to the wound, while maintaining low trauma properties. The adhesive may be applied only along at least two opposed sides of a border portion of the facing layer (col. 15, lines 13-14). The adhesive layer may be apertured (see Figure 1). The adhesive layer may be acrylate glue (see col. 11, lines 36-61).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the wound dressing disclosed by Levin, wherein the adhesive layer is a pressure sensitive adhesive applied to the facing layer, as taught by Stickles et al., to provide an adhesive layer that provides a secure adhesion to the wound, while maintaining low trauma properties.

6. Claims 1 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin in view of U.S. Patent Number 6,103,369 to Lucast et al.

Levin discloses a wound dressing comprising:

an absorbent core (26) having opposed proximal and distal surfaces including central and border (edges) portions;

a discrete skin adherent, elastomeric gel facing layer (22) having a distal surface secured to the proximal surface of the absorbent core, said facing layer having a plurality of through extending apertures (24) arranged in a pattern; and

a discrete adhesive layer (40) applied adjacent the facing layer to secure the dressing to the wound. Levin does not specify that the adhesive that secures the dressing to the wound be a pressure sensitive adhesive layer applied to the proximal surface of the facing layer.

Lucast et al. disclose a wound dressing including a discrete pressure sensitive silicone gel adhesive layer applied to the facing layer of the wound dressing, to provide a dermatologically acceptable adherence to the skin (col. 7, lines 6-18). The claimed phrase “sprayed onto the facing layer” is being treated as a product by process limitation.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Lucast et al. is silent as to the process used to apply the silicone gel to the wound dressing, it appears that the product in Lucast et al. would be the same or similar as that claimed.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the wound dressing disclosed by Levin, wherein the adhesive layer is a pressure sensitive silicone gel adhesive applied to the facing layer, as taught by Lucast et al., to provide a dermatologically acceptable adherence of the wound dressing to the skin.

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7. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin in view of U.S. Patent Number 5,540,922 to Fabo and in view of U.S. Patent Number 6,566,575 to Stickels et al.

Levin discloses a wound dressing comprising:

an absorbent core (26) having opposed proximal and distal surfaces including central and border (edges) portions;

a facing layer (22) comprising a gel and having a distal surface directly secured to the proximal surface of the absorbent core, said facing layer having a plurality of through extending apertures (24) arranged in a pattern; and

a discrete adhesive layer (40) applied adjacent the facing layer to secure the dressing to the wound. The apertures of the facing layer are substantially equally spaced and uniform in shape (see Figure 1).

Levin does not specify that the gel facing layer is cross-linked silicone or that the adhesive that secures the dressing to the wound be a pressure sensitive adhesive layer applied to the proximal surface of the facing layer.

Fabo discloses a wound dressing comprising an absorbent core (5), and a facing layer (2) comprising a gel and having a plurality of through extending apertures (24) arranged in a pattern. Fabo specifies that the gel facing layer be cross-linked silicone, for its soft and hydrophobic properties.

Stickels et al. disclose a wound dressing comprising an absorbent core (12); a discrete facing layer (20) having a distal surface secured to the proximal surface of the absorbent core, said facing layer having a plurality of through extending apertures (24) arranged in a pattern; and a discrete pressure sensitive adhesive layer applied to the facing layer on at least a segment



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of a proximal surface thereof, to provide a secure adhesion of the dressing to the wound, while maintaining low trauma properties. The adhesive layer does not occlude the apertures of the facing layer.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the wound dressing disclosed by Levin, wherein the gel facing layer is a silicone gel and wherein the adhesive layer is a pressure sensitive adhesive applied to the facing layer, as taught by Fabo and Stickles et al., to provide a soft hydrophilic gel layer, and an adhesive layer that provides a secure adhesion to the wound, while maintaining low trauma properties.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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